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Practitioner's Docket No. 101078.0001US3

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: BabakNemati

Application No.: 09/777,640 Group No.: 3763

Filed: 02/07/2001 Examiner: Michael J Hayes

For: Method and Apparatus to Enhance Optical Transparency of Biological Tissues

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TRANSMITTAL OF APPEAL BRIEF
(PATENT APPLICATION--37 C.F.R. § 1.192)

1. Transmitted herewith, in triplicate, is the APPEAL BRIEF in this application, with respect to the Notice of Appeal filed on July 20, 2004.

2. STATUS OF APPLICANT

This application is on behalf of a small entity.

3. FEE FOR FILING APPEAL BRIEF

Pursuant to 37 C.F.R. § 1.17(c), the fee for filing the Appeal Brief is $165.00.

Appeal Brief fee due $165.00

4. EXTENSION OF TERM

The proceedings herein are for a patent application and the provisions of 37 C.F.R. § 1.136 apply.

Applicant believes that no extension of term is required. However, this conditional petition is being made to provide for the possibility that applicant has inadvertently overlooked the need for a petition and fee for extension of time.

CERTIFICATE OF EXPRESS MAILING OR MAILING (37 C.F.R. section 1.10/1.8(a))

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the united States Postal Service on the date shown below with sufficient postage as Express Mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, bearing label no. EV607355526US.

Date: 9/16/04

Collene Houston

5. TOTAL FEE DUE

Appeal brief fee	$165.00
Extension fee (if any)	$0.00
TOTAL FEE DUE	**$165.00**

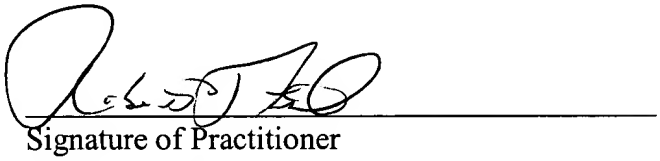
6. FEE PAYMENT

Authorization is hereby made to charge the amount of $165.00 to Deposit Account No. 502191.

7. FEE DEFICIENCY

If any additional extension and/or fee is required, and if any additional fee for claims is required, charge Deposit Account No. 502191.

Date: 9/16/09



Signature of Practitioner

Reg. No.: 33,880
Tel. No.: 714-641-5100
Customer No.: 34284

Robert D. Fish
Rutan & Tucker, LLP
P.O. Box 1950
611 Anton Blvd., 14th Floor
Costa Mesa, CA 92628-1950

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
GROUP ART UNIT 3611

EXAMINER:	Hayes, Michael J.
APPELLANT:	Babak Nemati
SERIAL NO.	09/777,640
FILED:	February 7, 2001
FOR:	Method and Apparatus to Enhance Optical Transparency of Biological Tissues
ART UNIT	3763

MS Appeal Brief - Patents
Commissioner of Patents and Trademarks
Washington, D.C. 20231
Attention: Board of Patent Appeals and Interferences

APPELLANT'S BRIEF UNDER 37 CFR § 1.192

This brief, transmitted in triplicate, follows the appellant's Notice of Appeal filed in this case on July 20, 2004.

The fees required under § 1.17, and any required petition for extension of time for filing this brief and fees therefor, are dealt with in the accompanying TRANSMITTAL OF APPEAL BRIEF.

This brief contains the following items under the headings in the order here indicated:

I. Real Party In Interest

II. Related Appeals And Interferences

III. Status Of Claims

IV. Status Of Amendments

V. Summary Of Invention

VI. Issues

VII. Grouping Of Claims

VIII. Arguments

IX. Appendix of Claims

I. Real Party In Interest

The real party in interest is the Applicant, Babak Nemati.

II. Related Appeals And Interferences

There are no other appeals or interferences in this matter known to appellant.

III. Status Of Claims

1. Claims canceled: 1-70;
2. Claims pending: 71-90;
3. Claims rejected: 71-90; and
4. Claims on appeal: 71-90.

IV. Status Of Amendments

No amendments were filed after final rejection. The claims were rejected in the final office action based on amendments entered in response to the previous non-final office action. Section IX recites the claims as entered/pending and under final rejection.

V. Summary Of Invention

The invention is directed to an apparatus for an *in vivo* procedure (see *e.g.*, specification pages 20-22; Figure 6) comprising a pore forming portion that is configured to create an opening in a permeability barrier (see *e.g.*, specification, page 15, second paragraph), wherein the opening is configured to allow delivery of a clarifying agent to a tissue disposed below the permeability barrier (see *e.g.*, specification, page 16, second paragraph); wherein the clarifying agent enhances optical transparency of the tissue disposed below the permeability barrier to thereby form an area of clarified tissue (see *e.g.*, page 14, first and second paragraphs, Figures 4 and 5). The apparatus

further includes a delivery portion coupled to the pore forming portion (see *e.g.*, specification, page 19, fourth paragraph; Figure 6), wherein the delivery portion is configured to allow dispensing the clarifying agent from the delivery portion to the tissue disposed below the permeability barrier through the opening (see *e.g.*, specification page 19, fourth paragraph; Figure 6). The apparatus still further includes an optical portion coupled to at least one of the pore forming portion and the delivery portion and configured such that light emitted by the optical portion passes through the permeability barrier or opening to an area within or below the area of clarified tissue disposed below the permeability barrier (see *e.g.*, specification page 19, fifth paragraph; Figure 6), wherein the apparatus is configured such that the opening is formed, the clarifying agent is delivered, and the light is emitted when the apparatus is in a position proximal to the sclera (see *e.g.*, Figure 6, claims 30 and 50 as originally filed).

VI. Issues

1. Whether claims 74 and 79 should have been rejected under 35 U.S.C. § 112 as lacking enabling support (Final Office Action, paragraph spanning pages 2 and 3).

2. Whether claims 78 and 80-90 should have been rejected under 35 U.S.C. § 102 as being anticipated by Martinez (U.S. Pat. No. 4,222,375) (Final Office Action, page 3).

3. Whether claims 71-90 should have been rejected under 35 U.S.C. § 103 as being obvious over Chan (U.S. Pat. No. 6,275,726) in view of Martinez (U.S. Pat. No. 4,222,375) (Final Office Action, pages 3 and 4).

4. Whether claims 79 should have been rejected under 35 U.S.C. § 103 as being obvious over Martinez (U.S. Pat. No. 4,222,375) in view of Edwards (U.S. Pat. No. 5,833,647) (Final Office Action, pages 3 and 4).

VII. Grouping Of Claims

Claims 71-77, 78-85, and 86-90 stand or fall together.

VIII. Argument

Background

On **February 7, 2001**, the appellant filed application no. 09/777,640 for Method and Apparatus to Enhance Optical Transparency of Biological Tissues, which was finally rejected **May 15, 2003**.

A request for continued examination was filed **November 12, 2003** concurrent with an amendment in which claims 1-36 remained canceled, in which previously pending claim 37 was amended, and in which claim 70 was added.

On **December 17, 2003** the Office rejected claims 37, and 45-70 as failing to comply with the enablement requirement. Claims 37-56, 62, and 69 were also rejected as being anticipated by Martinez as the referenced device would supposedly be able to perform the functions as claimed. Claims 37-52, 54-65, 62-64, 66, and 69 were further rejected as being obvious over Chan for allegedly reciting elements that would be inherent in the use of Chan's device. Claims 53, 57-59, 61, 65, 67, and 70 were also rejected as being obvious over Martinez in view of Edwards for claiming subject matter allegedly suggested by Martinez and Edwards. Similarly, claims 60 and 68 were rejected as being obvious over Martinez in view of Weaver for claiming subject matter allegedly suggested by Martinez and Weaver.

In a telephone interview with the Examiner on **March 12, 2004**, the applicant discussed a revised set of claims that addressed the previously raised issues. No agreement was reached and the Examiner pointed out that the claimed device must show a structural difference with the prior art or a function that the prior art is not capable of performing.

On **March 16, 2004**, the applicant filed a response to the office action in which the claims were amended to address the Examiner's concerns. Specifically, previously pending claims 37-70

were canceled and the added claims 71-90 expressly required (among other elements) that the apparatus is configured such that all claimed subsystems are operated when the apparatus is in a proximal position to the barrier, and/or that the optical portion is a non-invasive portion. Further, the claims as amended now included three sets of independent claims (including ophthalmologic and dermatologic apparatus).

On **June 9, 2004** the Office finally rejected all pending claims on various grounds with arguments substantially similar to the office action dated December 17, 2003. Claims 74 and 79 were rejected as failing to comply with the enablement requirement. Claims 78, and 80-90 were further rejected as being anticipated by Martinez as the reference device would supposedly be able to perform the functions as claimed. Claims 71-90 were also rejected as being obvious over Chan in view of Martinez for claiming subject matter allegedly suggested by Chan and Martinez. Similarly, claim 79 was rejected as being obvious over Martinez in view of Edwards for claiming subject matter allegedly suggested by Martinez and Edwards.

The applicant disagrees with the Examiner's positions presented in the final office action. However, the applicant did not file a response after final as the applicant felt that the Examiner has continuously failed to properly apply pertinent law and would not change his position in light of newly presented arguments. Consequently, the applicant filed a notice of appeal on **July 20, 2004**.

Issue No. 1 – U.S.C. § 112 , first paragraph

The Examiner rejected, in the final Office Action dated June 6, 2004, claims 74 and 79 under 35 U.S.C. § 112 as lacking enabling support. More specifically, the Examiner alleges that the applicant has not described how to combine an optical portion with iontophoresis, electroporation, acoustic pressure application or a laser irradiation pore forming portion to enable its use or manufacture. The applicant disagrees for various reasons.

Incorrect/Inconsistent Assertion by the Examiner

First, as pointed out in the specification, each of the components in the claimed device is known *per se* in the art. This assertion was not contradicted by the Office, and the medical device field is replete with such components *per se*. It is the applicant's position that it is well within the purview of the person of ordinary skill in the art of medical device manufacturing to couple the

claimed components in a manner as claimed. Additionally, Figure 6 provides sufficient guidance as to one exemplary co-axial coupling. For example, the tip of Tissue Bypass Apparatus portion of Figure 6 may include one or more electrodes for iontophoresis or electroporation, or an ultrasound transducer for acoustic pressure application, or a light guide for laser irradiation. Such a Tissue Bypass Apparatus portion is clearly depicted as being in at least partial co-axial arrangement relative to the Optical Deliver Apparatus portion. Thus, claims 74 and 79 are clearly enabled by the specification and the knowledge of a person of ordinary skill in the art.

Second, in his obviousness rejection of claims 71-90 in the same office action, the Examiner relies on just that skill of the person of ordinary skill in the art to combine Chan with Martinez. On page 4, the Examiner states that "...Chan does not disclose the fluid delivery device and light delivery device in one apparatus...[and that]...it would have been obvious to one of ordinary skill in the art...to use the teachings of Martinez in the apparatus of Chan..." Thus, it is the Examiner's own position that the combination of the components must be within the range of skills of a person of ordinary skill in the art.

Issue No. 2 – U.S.C. § 102(b)

Claims 78 and 80-90 were rejected in the final Office Action dated June 6, 2004 under 35 U.S.C. § 102(b) as being anticipated by Martinez. More specifically, the Examiner asserts that the apparatus taught by Martinez would be "...capable of enhancing the optical transparency of a biological tissue comprising means for bypassing the surface barrier..., means for delivering clarifying agent..., means for delivery of light..." and further states that "...the various uses recited in the claims are readable on the prior art because the prior art is capable of performing these functions and supplying light for these functions..." The applicant disagrees for various reasons.

Failure To Acknowledge Express Elements In Applicant's Claims

It is well established that "...A claim is anticipated only if ***each and every element as set forth in the claim*** is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). This is also reflected in Richardson v. Suzuki Motor Co. in which the court held that "...The ***identical invention must be shown in as complete detail as is contained in the ... claim***." Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

First, the applicant points out that claims 78 and 86 (and claims 80-85 and 87-90 by virtue of their dependence on claim 78 and 86, respectively) expressly require a "...***non-invasive optical portion***..." Such element is clearly not taught by Martinez. In fact, Martinez teaches a use of a cannula to insert a fiber optic into a patient's body, which by it's very nature is an invasive device (see *e.g.*, column 3, lines 53 *et seq.*).

Second, the applicant points out that claim 78 (and claims 80-85 by virtue of their dependence on claim 78) expressly requires that the "...***apparatus is configured such that*** the ***clarifying agent is driven through the permeability barrier*** and the ***light is emitted to the area when the apparatus is in a position proximal to the tissue*** disposed below the permeability barrier..." Once more, such an element is clearly not taught by Martinez. Again, and on the contrary to the claimed apparatus, Martinez' device is used to insert a fiber optic bundle into a patient's body using a cannula, wherein the cannula is configured to deliver or remove a fluid. Clearly, such action is taken by Martinez when the cannula is inserted into the body and not from a position proximal to the observed tissue.

Similarly, claim 86 (and claims 87-90 by virtue of their dependence on claim 86) expressly requires that the "...***apparatus is configured such*** that the ***opening is formed***, the ***clarifying agent is delivered, and the light is emitted when the apparatus is in a position proximal to the tissue disposed below the stratum corneum***..." Such an element is not taught by Martinez. Again, and on the contrary to the claimed apparatus. First, Martinez' device requires that an opening is first formed through which the device is then inserted. Second, Martinez' device delivers light directly to the tissue and not from a position proximal to the observed tissue. For at least these reasons, claims 78 and 80-90 should not be held anticipated by Martinez.

Issue No. 3 – U.S.C. § 103(a)

Claims 71-90 were rejected in the final Office Action dated June 6, 2004 under 35 U.S.C. § 103 as being obvious over Chan in view of Martinez. More specifically, the Examiner alleges that "...Chan discloses means for bypassing the surface permeability barrier, means for delivering a clarifying agent, means of light delivery for diagnostic and therapeutic applications, and a device to provide spectral information. When using the ink jet embodiment disclosed by Chan, the device is

non-invasive and is capable of remaining proximal to the barrier..." The Examiner further indicates that Chan fails to disclose the combination of a fluid delivery device and a light delivery device in one apparatus, and concludes that "...It would have been obvious...to use the teachings of Martinez in the apparatus of Chan to accomplish the precise application of light..." Once more the applicant disagrees for various reasons.

Failure To Acknowledge Express Elements In Applicant's Claims

It should be trivial to note that each and every element of a claim must be addressed. However, it appears that the Examiner in his rejections attempts to ignore that [for claims 71-77] the "...***apparatus is configured such*** that the ***opening is formed***, the ***clarifying agent is delivered***, and the ***light is emitted when the apparatus is in a position proximal to the sclera***...", [for claims 78-85] the "...***apparatus is configured such that*** the ***clarifying agent is driven through the permeability barrier*** and the ***light is emitted to the area when the apparatus is in a position proximal to the tissue*** disposed below the permeability barrier...", and [for claims 86-90] the "...***apparatus is configured such*** that the ***opening is formed***, the ***clarifying agent is delivered***, and the ***light is emitted when the apparatus is in a position proximal to the tissue disposed below the stratum corneum***...". These express elements are neither taught nor suggested by Chan or Martinez. Similarly, neither Chan nor Martinez teach or suggest the use of a ***non-invasive optical portion*** as expressly required by claims 78-90. Therefore, not all of the elements are taught or suggested by the cited references.

Failure to Acknowledge Teaching Away/Against Claimed Subject Matter

With respect to Martinez, the applicant points out that Martinez' device is based on a cannula through which a fiber optic is threaded to illuminate or examine a target tissue. There is simply no teaching, suggestion, or motivation to use Martinez' device in a manner as presently claimed. On the contrary, the '375 reference specifically elaborates that the cannula is "...***adapted for insertion in a body***..." (column 1, line 68). Furthermore, the cannula has a fluid port to allow infusion or evacuation of a space in a body of a patient. Clearly, ***if Martinez' device was intended for non-invasive use, such fluid port would not be present***. Thus, Martinez teaches at least away, if not even against the subject matter as presently claimed.

With respect to Chan, it should be pointed out that Chan is concerned with index matching of tissue fluids, and that the only optical instrument taught or suggested by Chan is a laser or other light source to illuminate clarified tissue. However, there is absolutely no teaching or suggestion to couple such slight source to a pore forming portion and a fluid delivery portion. On the contrary, ***fluid delivery taught by Chan is via injection or soaking of an excised piece of tissue***, which clearly teaches away, if not even against the claimed subject matter. Similarly, Chan teaches pore forming using dermabrasion (*e.g.*, tape stripping) or chemical peels, which further teaches away from the claimed subject matter. No combination of Chan and Martinez will remedy the above listed defects.

The Examiner has failed in his rejections to properly point out where in the references a motivation or suggestion would be present to combine the teachings such as to arrive at the subject matter presently claimed. Instead, the Examiner maintained in his response to the applicant's arguments"...the limitation is directed to the use of the device and if the prior art is capable of this use then the claims read on the prior art. Martinez is capable of this use...". Once more, the Examiner chose to ignore several specific limitations that are contrary to Martinez' teachings.

Issue No. 4 – U.S.C. § 103

Claim 79 was rejected in the final Office Action dated June 6, 2004 under 35 U.S.C. § 103 as being obvious over Martinez as applied before and further view of Edwards. The applicant disagrees for various reasons. As claim 79 is dependent on claim 78, the same argument as provided above applies. Edwards cannot remedy such defects as Edwards teaches enhancing mass transfer through a hydrogen or lipogel to skin. Thus, any transport taught by Edwards does not focus on delivery of a molecule to a covered biological tissue, but instead deals with mass transport through a non-skin component (*i.e.*, hydrogel or lipogel). It remains unclear to the applicant how Edwards could be properly applied to reject claim 79.

Conclusion Of Argument

In rejecting the presently pending claims, the Office failed to provide conclusive argument as to why selected claims would not be enabled, especially in view of the Examiner's subsequent obviousness allegation. The Office further failed to acknowledge express elements in applicant's claims, and based on that failure rejected selected claims as being anticipated and/or obvious over various references. Based on the arguments provided above, it is the applicant's position that the rejections should be withdrawn.

Respectfully submitted,

Dated: September 16, 2004

Robert D. Fish
Reg. No. 33,880
Agent for Appellant

Rutan & Tucker, LLP
P.O. Box 1950
611 Anton Blvd., Suite 1400
Costa Mesa, CA 92628-1950
Tel: 714-641-5100
Fax: 714-546-9035

APPENDIX

71. (Previously presented) An apparatus for an *in vivo* ophthalmologic procedure comprising:

a pore forming portion that is configured to create an opening in a conjunctiva, wherein the opening is configured to allow delivery of a clarifying agent to a sclera disposed below the conjunctiva;

wherein the clarifying agent enhances optical transparency of the sclera to thereby form an area of clarified sclera;

a delivery portion coupled to the pore forming portion, wherein the delivery portion is configured to allow dispensing the clarifying agent from the delivery portion to the sclera through the opening;

an optical portion coupled to at least one of the pore forming portion and the delivery portion and configured such that light emitted by the optical portion passes through the conjunctiva or opening to an area within or below the area of clarified sclera; and

wherein the apparatus is configured such that the opening is formed, the clarifying agent is delivered, and the light is emitted when the apparatus is in a position proximal to the sclera.

72. (Previously presented) The apparatus of claim 71 wherein the pore forming portion and the optical portion are coaxially arranged relative to each other.

73. (Previously presented) The apparatus of claim 71 wherein the optical portion comprises at least one of a confocal microscope and a device that provides spectral information from a fluid in the clarified sclera.

74. (Previously presented) The apparatus of claim 71 wherein the pore forming portion employs mechanical force or laser irradiation to create the opening.

75. (Previously presented) The apparatus of claim 71 wherein the clarifying agent is selected from the group consisting of diatrizoate meglumine acid, glycerol, and glucose.

76. (Previously presented) The apparatus of claim 71 wherein the light is visible light.

77. (Previously presented) The apparatus of claim 71 wherein the light has a wavelength and energy sufficient for photocoagulation or photodynamic therapy.

78. (Previously presented) An apparatus for an *in vivo* medical procedure comprising:

a driver portion that is configured to drive a clarifying agent through a permeability barrier to a tissue disposed below the permeability barrier;

wherein the clarifying agent enhances optical transparency of the tissue to thereby form an area of clarified tissue;

a non-invasive optical portion coupled to the driver portion and configured such that light emitted by the optical portion passes through the permeability barrier to an area within or below the area of clarified tissue; and

wherein the apparatus is configured such that the clarifying agent is driven through the permeability barrier and the light is emitted to the area when the apparatus is in a position proximal to the tissue disposed below the permeability barrier.

79. (Previously presented) The method of claim 78 wherein the driver portion is configured to drive the clarifying agent across the permeability barrier by iontophoresis, electroporation, application of acoustic pressure, or application of a chemical enhancer, a carrier agent, or a penetrating solvent.

80. (Previously presented) The method of claim 78 wherein the permeability barrier comprises a conjunctiva.

81. (Previously presented) The method of claim 78 wherein the light is delivered to an area below the area of clarified target tissue.

82. (Previously presented) The method of claim 78 wherein the light has a wavelength and energy sufficient for photocoagulation or photodynamic therapy.

83. (Previously presented) The method of claim 78 wherein the permeability barrier comprises a stratum corneum.

84. (Previously presented) The method of claim 78 wherein the optical portion is further configured to acquire an analyte signal from an analyte disposed within the area of clarified tissue.

85. (Previously presented) The method of claim 78 wherein the clarifying agent is selected from the group consisting of diatrizoate meglumine acid, glycerol, and glucose.

86. (Previously presented) An apparatus for an *in vivo* dermatological procedure comprising:

a pore forming portion that is configured to create an opening in a stratum corneum, wherein the opening is configured to allow delivery of a clarifying agent to a tissue disposed below the stratum corneum;

wherein the clarifying agent enhances optical transparency of the tissue to thereby form an area of clarified tissue;

a delivery portion coupled to the pore forming portion, wherein the delivery portion is configured to allow dispensing the clarifying agent from the delivery portion to the tissue through the opening;

a non-invasive optical portion coupled to at least one of the pore forming portion and the delivery portion and configured such that visible light emitted by the optical portion passes through the stratum corneum or opening to an area within or below the area of clarified tissue; and

wherein the apparatus is configured such that the opening is formed, the clarifying agent is delivered, and the light is emitted when the apparatus is in a position proximal to the tissue disposed below the stratum corneum.

87. (Previously presented) The apparatus of claim 86 wherein the pore forming portion and the optical portion are coaxially arranged relative to each other.

88. (Previously presented) The apparatus of claim 86 wherein the visible light has a wavelength of between 350 nm to 750 nm.

89. (Previously presented) The apparatus of claim 86 wherein the clarifying agent is selected from the group consisting of diatrizoate meglumine acid, glycerol, and glucose.

90. (Previously presented) The apparatus of claim 86 wherein the clarifying agent further includes an enhancing agent selected from the group consisting of a chemical enhancer, a carrier agent, and a penetrating solvent.